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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/24/2003

George Goicoechea

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P.O. BOX 980

VALLEY FORGE, PA 19482

EXAMINER

WOO, JULIAN W

ART UNIT

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3773

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,886	Applicant(s) GOICOECHEA ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-81,84,95-106,110-112 and 129-133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-81,84,95-106,110-112 and 129-133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 17, 2009 has been entered.

Claim Objections

2. Claim 132 and the specification are objected to because of an informality, which can be corrected as follows: "[A]ngeological" should be replaced by --angiological--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 132 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "A system...of claim 133" lacks antecedent basis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3773

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 72-78, 81, 84, and 96-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon et al. (5,084,065) in view of Barone et al. (5,360,443).

Weldon et al. disclose the invention substantially as claimed. Weldon et al. disclose, at least in figures 2-6 and col. 5, line 1 to col. 6, line 68; a graft including a primary graft body (21 and/or 31) or second graft body having a primary graft flow lumen and first and second portions; where the primary graft body is carried by a plurality of wire hoops (44 or 34, i.e. multiple, interwoven coils of filaments) comprising two opposing ends, the ends being joined together on the outside surface of the primary graft body, where the wire hoops are attached to the primary graft body via sutures, where one of the wire hoops is located at one end of the primary graft body and has alternate apices (34b) extending beyond one end of the primary graft body, where the primary graft body is formed of thin biocompatible material, where the second graft body is a multi-layered graft body, and a wire structure (34) is sandwiched between layers of the multi-layered graft body; where the wire structure (44) is disposed at least in part on an outside surface of the respective surface of a graft body, where the wire structure (24, if 31 is

Art Unit: 3773

deemed a graft body) is disposed substantially on an inside surface of graft body, and where the wire structure is interwoven with the surface of a graft body (e.g., via sutures). However, Weldon et al. do not disclose a supplemental or first graft body having a flow lumen and first and second ends, the first end of the supplemental graft body being dockable to a second portion of the primary graft body while inside of a vessel, where the supplemental graft body is carried by a plurality of wire hoops, where the wire hoops are attached to the supplemental graft body via sutures, where the supplemental graft body is formed of a thin biocompatible material, where the second graft body is made of PTFE. Barone et al. teach, at least figures 1-4 and col. 5, line 40 to col. 7, line 19; a supplemental (166) or first graft body having a flow lumen and first and second ends, the first end of the supplemental graft body being dockable to a second portion of a primary (160) or second graft body while inside of a vessel, where the supplemental graft body is carried by the primary graft body, where the primary graft body is attached to the supplemental graft body via sutures (170), where the supplemental graft body is formed of a thin biocompatible material, where the second graft body is made of PTFE. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Barone et al., to include a supplemental or first graft body as claimed with the primary or second graft body of Weldon et al. Such a modification would allow the firm anchorage of graft bodies at a wall surface of an aorta for the repair of an aortic aneurysm. Also, it would have been obvious to one having ordinary skill in the art to form the second graft body out of PTFE. Such a material has the requisite strength and biocompatibility for use as a graft

Art Unit: 3773

material. Moreover, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

7. Claims 79, 80, 95, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon et al. (5,084,065) in view of Barone et al. (5,360,443), and further in view of Wallsten (4,655,771). Weldon et al. in view of Barone et al. disclose the invention substantially as claimed, but do not disclose wire hoops having a different amplitude than the next adjacent wire hoop, where the wire structure is formed of metal or is X-ray detectable. Wallsten teaches, at least in figures 1a and 9 and in col. 2, lines 44-56; a prosthesis with wire hoops or a wire structure, where wires are spaced apart and form sinuous structures having an amplitudes. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wallsten, to modify the hoops or structure of Weldon et al. in view of Barone et al.. Such wires would allow the graft to be more flexible for its deployment through a blood vessel, and they would allow secure fixation of the graft to the wall of the blood vessel. Moreover, it would be a matter of obvious design choice to configure the wires, so that at least one of the wires has a different amplitude than the next adjacent wire. The choice would be dependent upon the desired length and flexibility for the graft. Wallsten also teaches, in col. 3, lines 20-28; that the wire may be formed of metal. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wire structure, so that it is formed of metal. Such a material would have the requisite strength and flexibility for a graft, and the metallic material would allow for X-

Art Unit: 3773

ray detection for imaging and positioning of the graft. Moreover, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. Claims 103-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon et al. (5,084,065) in view of Barone et al. (5,360,443), and further in view of Porter (5,064,435). Weldon et al. in view of Barone et al. disclose the invention substantially as claimed. Weldon et al. in view of Barone et al. disclose first and second graft bodies as claimed (see paragraph 6 above), where the second graft body is substantially cylindrical, but do not disclose that the second graft body is frustoconical in shape and has a length of about 18 mm. Porter teaches, in figure 1 and col. 5, lines 13-25; a substantially cylindrical graft body (20 or 22) including a frustoconical shape (34 or 36). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Porter, to modify the second graft body, so that an end portion includes a frusto-conical shape. Such a shape would provide a fixation feature for the graft, so that it can be affixed to a blood vessel with a lumen portion that is flaring in configuration. Also, it would have been a matter of design choice to size the frustoconical portion as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

9. Claims 110, 112, and 131-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barone et al. (5,360,443) in view of Weldon et al. (5,084,065).

Art Unit: 3773

Barone et al. disclose the invention substantially as claimed. Barone et al. disclose, at least in figures 1-4 and col. 5, line 40 to col. 7, line 19; and col. 9, lines 19-51; a graft including a first graft (166) having a proximal end, a distal portion, and a flow passage; a secondary graft body (160) having proximal portion, a distal portion, and flow passage; where the second graft body is carried by a metal wire structure (of element 166), the graft comprising a male engaging portion on the first graft body inter-engaged with a female portion on the second graft body (at 61), the male engaging portion and the female portion comprising a stent; where the wire structure (166) comprises at least one wireform or a plurality of wireforms, and where a system with the graft includes first and second introducers (201). However, Barone et al. do not disclose a graft layer attached to the stent and configured to be interposed between the male engaging portion and the female portion. Weldon et al. teach, in col. 2, lines 28-53; a stent (21) with a graft layer (e.g., 31 and/or 41). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Weldon et al. to include a graft layer with the stent of Barone et al. Such a layer would reinforce the stent at a section at the interface, i.e., a stress concentration, between male and female portions of the stent.

10. Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barone et al. (5,360,443) in view of Weldon et al. (5,084,065), and further in view of Wallsten (4,655,771). Barone et al. in view of Weldon et al. disclose the invention substantially as claimed, but do not disclose that the at least one wireform has a sinuous configuration. Wallsten teaches, at least in figures 1a and 9 and in col. 2, lines 44-56; a prosthesis with at least one wireform, where the wireform is in sinuous

Art Unit: 3773

configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Wallsten, to modify the wireforms of Barone et al. in view of Weldon et al., such that they are sinuous in configuration. Such wireforms would allow the graft to be more flexible for its deployment through a blood vessel, and they would allow secure fixation of the graft to the wall of the blood vessel. .

11. Claims 129 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barone et al. (5,360,443) in view of Weldon et al. (5,084,065), and further in view of Porter (5,064,435). Barone et al. in view of Weldon et al. disclose the invention substantially as claimed, but do not disclose radiopaque markers as claimed. Porter teaches, in col. 6, lines 7-17; the application of one or more radiopaque markers on graft 16. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Porter, to apply radiopaque markers as claimed to the graft of Barone et al. in view of Weldon et al. Such markers would allow imaging, proper positioning, and position confirmation for the graft during and after intravascular insertion of the graft.

Response to Amendment

12. Applicant's arguments with respect to claims 72-81, 84, 95-106, 110-112, and 129-133 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

Art Unit: 3773

4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773